REMARKS

The last Office Action of June 25, 2008 has been carefully considered. Reconsideration of the instant application in view of the foregoing amendments and the following remarks is respectfully requested.

Claims 2-21 are pending in the application. Claims 1-3 and 6-12 are currently under examination. Claims 4, 5 and 13-20 are currently withdrawn from consideration. Claims 2-3 and 6-12 have been amended. Claim 1 has been cancelled. A new Claim 21 has been added. A total of 10 claims is now on file. An amendment to the specification has been made. No fee is due.

The Examiner has objected to the use of the sequence names as recited in the claims.

The Examiner has also objected that no required statement as to CRF and the paper form of the sequence listing ahs been provided.

The Examiner also objected to claim 1-3 and 6-12 on the basis of lack of infinite or definite article, to claim 1 for the second occurrence of "but not identical", to claim 8 for the recitation of "the single strands" without antecedent basis.

The Examiner also objected to the specification in connection with the recitation on page 20 of http://www.kazusa.or.ip/codon and page 25 http://www.fruitfly.org.seg tools/html.

It is further noted that claim 1 and dependent claims 2, 3 and 6-12 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 6, 8 and 12 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No.: 6,248,582 to Khan ("Khan").

Claims 1, 9-11 are rejected under 35 U.S.C. §103(a) as being obvious over Khan in view of the Schirmbeck et al. publication (June 2001) J. Mol. Med., Vol. 79, pp. 343-350 ("Schirmbeck").

Claim 3 stands rejected under Khan in view of Schirmbeck and further in view of U.S. patent No.: 6,696,291 to Shiver ("Shiver"), the publication to Laprevotte J. Virol. , pp884-894; the Genbank accession No.: K01803, FeLV gag cDNA) and Garner–Arnstein feline leukemia oncovirus codon usage (www.kazusa.or.jp./codon, of record).

CLAIM OBJECTION

Applicant has amended the claims in order to avoid the Examiners' objection, whereby "but not identical", 2nd occurrence was deleted and in claim 8 the antecedent basis was also corrected.

SPECIFICATION OBJECTION

The specification was amended to delete the offensive hyperlink references.

REJECTION OF CLAIMS 1, 2, 3 AND 6-12 UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Applicant has deleted the parenthetical matter in claims 1, 2, 3, and 6-12 page 20 and page 25 of the specification such that the rejection thereof is now moot.

Claims 1 and 12 recited the offensive phrase "and/or". Applicant has replaced that phrase with the Phrase" at least one of .....and ....." which incorporates in that manner the conjunctive and the disjunctive. Thus, the rejection based indefiniteness is believed to have been overcome. Since claims 2, 3 and 6-11 are directly or indirectly dependent on claim 1 or claim 12, this rejection has been likewise overcome.

Withdrawal of the rejection of claims 1, 2, 3 and 6-12 under 35 U.S.C. §112, second paragraph is respectfully requested.

REJECTION OF CLAIM 1, 2, 6, 8 AND 12 UNDER 35 U.S.C. §102(b) AS BEING ANTICIPATED BY KHAN

The rejection under 35 U.S.C. 102(b) is respectfully traversed.

Khan discloses an expression cassette having a shortened FeLV sequence where mutated "pol" and "env" gene sequences are utilized. This is to be differentiated from the present claim 21.

With the mutated gene "pol" there is no codon optimization or splice/donor site deletion in accordance with the present invention. The Kahn mutations are non-functional mutations, (see col. 6, line 33). Clearly those Khan mutations are not directed to "gag" and "env" but the viral "pol" and the deletion of its integrase function (co. 3, lines 3-4).

While the Examiner points to col. 2, lines 45-55 and col. 3, lines 1-15 as a basis for the rejection, the referred to statements are not directed to a mutation in the "gag" and "env" genes. In col. 2, lines 45-55 simply a shortening of the FeLV genome is referenced, while in col. 3, lines 1-15 the deletion of the "pol" gene is disclosed in addition to the complete unmodified "gag" and "env". This does not amount to a basis to hold claim 1 and the claims dependent thereon as anticipated.

The Examiner admits that Khan does not explicitly teach that plasmid vectors comprise no acceptor sequences. The Examiner then postulates that on any primary transcript expressing a variant of "gag" and/or "env" protein is intrinsically necessary as demonstrated by the generation of antibody specific to expressed truncated forms of said peptides. However, the referred to modification is simply a shortening by 150 base pairs (Example 6) and is unrelated to the codon optimized gene sequences as claimed. Khan is entirely silent on any "gag" modification. To anticipate a reference has to disclose each and every element of the claims. This is not the case here. Therefore Khan does not anticipate the claims.

Withdrawal of the rejection of claims 1, 2, 6, 8, and 12 under 35 U.S.C. §102(b) is thus respectfully requested.

REJECTION OF CLAIMS 1, 9-11 UNDER 35 U.S.C. §103(a) AS BEING ANTICIPATED BY KHAN IN VIEW OF SCHIRMBECK

The Examiner's rejection is respectfully traversed. Specifically, the Examiner alleges that Khan teaches expression cassettes encoding truncated forms of the feline leukemia virus proviral DNA including mutated forms of the "gag" and "env" genes citing col. 2, lines 45-55 and col. 3, lines 1-15. Neither in the 1st reference nor the 2nd reference is there any disclosure or teaching of the "gag" modification. In the 2nd reference only deletion of the "pol" gene is cited and expression of the non-modified "gag" and "env".

The Schirmbeck reference discloses the transfection and expression of a hepatitis B surface antigen (HbsAgAY) DNA sequence with a MIDGE vector and the coupling of a nuclear localization sequence in order to raise the transfection efficiency. As such Schirmbeck teaches a DNA sequence of a human virus which is unrelated to the FeLV virus.

Furthermore, Schirmbeck is completely devoid of a codon-optimization or deleting splice donor/acceptor sequences. Accordingly, Schirmbeck teaches a completely different biological system as compared to the one claimed here, which infects cat cells and not human cells. Schirmbeck does not teach or disclose any modification of the "gag" and "env" genes.

Since Schirmbeck is directed to a system for the efficient transfection and following immunization of humans with sequences of the human hepatitis B-Virus, Schirmbeck has nothing to do with vaccine for cats against the FeLV virus, whereby the sequences for "gag" and "env" are modified in a targeted way by means of codon optimization and deletion of splice-donor/acceptor-sequences.

While Schirmbeck teaches coupling of the nucleic acid sequence to be transfected with a NLS signal and utilization of the MIDGE-vector, the two systems are so distinct that there can be no expectation of success by merely by theorizing that the Schirmbeck system would work in the same manner in any other system, i. e. a vaccine related to the FeLV virus.

There is furthermore, no suggestion nor any motivation in Khan which would point to a successful combination. In particular, the Schirmbeck peptide sequence is completely different than the NLS sequence as claimed. The expectation of success for the ordinary person skilled in the art cannot be expected with these different systems. While the manipulation as postulated by the Examiner may sound simple; as is known from *In re Wand*, the art of replacing the nucleic acid sequence coding for the small antigen of hepatitis B in MIDGE vector for any other DNA sequence would be notoriously unpredictable. As such the rejection remains one with a hindsight approach, whereby certain elements are "plugged in" to show obviousness.

Based on the foregoing discussion, the combination of Khan and Schirmbeck fails to show that the claimed invention is obvious.

Withdrawal of the rejection of claims 1, 9-11 under 35 U.S.C. §103(a) is thus respectfully requested.

REJECTION OF CLAIM 3 UNDER 35 U.S.C. §103(a) AS BEING ANTICIPATED BY KHAN IN VIEW OF SCHIRMBECK AND FURTHER IN VIEW OF SHIVER, LAPREVOTTE, GENBANK ACCESSION AND GARNER-ARNSTEIN FELINE LEUKEMIA ONCOVIRUS

The Examiners' rejection is respectfully traversed.

The postulation by the Examiner is taking into account 6 references; in other words the array of 6 references is needed to cobble together the elements of claim 3. The sheer multitude of references indicates the weakness of the rejection, as discussed above the hindsight approach is the use of a template to which the elements of the various references are connected.

Here, the Examiner admits that Khan and Schirmbeck fail to teach a DNA expression construct contain a gag optimized nucleotide sequence. To fill for that the Examiner uses Shiver to fill the lacking elements. However Shiver is directed to HIV a human virus not related to FeLV virus. Shiver does not teach use of a codon-optimized "env" gene. As such the reference is lacking critical elements. An

essential part of the present invention is providing a vaccine for cats not just a successful transfection of any type cells with any type fragments of genes for membrane and structural proteins as in Shiver.

The Examiner even recognizes that when he states that *Shiver does not teach codon preferences of "env" and "gag" genes of FeLV in cats.* Therefore he cites Laprevotte and the disclosure of www.kazusa.or.jp./codon to claim that it would be obvious to optimize the wildtype FeLV nucleotide sequence as disclosed in Laprevotte. However, while the Laprevotte discloses the nucleotide sequence of the FeLV virus there is nothing more in the references that would lead those skilled in the art to modify the FeLV Genome and nothing in Laprevotte points to that. Contrary to the Examiners statement those of ordinary skill in the art would not start out with Khan, then look for Schirmbeck, go to Shiver and then Laprevotte and thereafter go to Gardner-Arnstein feline leukemia oncovirus codon usage with a reasonable expectation of success. While the references as the Examiner points out provide all the elements, the main references provide no teaching or suggestions that would point in the direction of the claimed invention. While the Supreme Court in *KSR* stated that there can be no rigid application of the teaching suggestion motivation test, nevertheless did not hold that such a test is abolished. Clearly, in the present case, neither Kahn not Schirmbeck point in the direction of the claimed invention and that the accumulation of the further references add nothing more in absence of a showing by the Examiner where such suggestion motivation or teaching is found.

In combination the following would result by the combination of relevant elements of the Schirmbeck Khan and Shiver references.

- MIDGE vector and NLS coupling of the expression construct form the hepatitis B context (Schirmbeck);
- an expression cassette comprising shortened "pol" and "env" gene sequences form the FeLV virus (Khan);
- Synthetic "gag" gene sequences form the HIV Genome and the use as immune stimulant against HIV- infection (Shiver).

The person skilled in the art cannot expect when using shortened "pol" and

"env" gene sequences from the FeLV virus in Kahn that the integration of the "gag" sequences lead to the claimed immunization effect. The use of synthetic "gag" sequences in Shiver does not render claim 3 obvious as both the virus and the host are from different species and thus are not taught.

Withdrawal of the rejection of claims 1, 9-11 under 35 U.S.C. §103(a) is thus respectfully requested.

PRIORITY

Applicant hereby submits an English translation of the prior submitted German priority document.

SEQUENCE LISTING

Applicant hereby states that the content of the paper copy and the computer readable copies are the same.

Regarding the requirement for the correct usage of nomenclature of the sequences i. e. SEQ ID NO. __ as they are claimed, applicant submits that were applicable the correct identification has now been used.

CONCLUSION

Applicant believes that when reconsidering the claims in the light of the above comments, the Examiner will agree that the invention is in no way properly met or anticipated or even suggested by any of the references however they are considered.

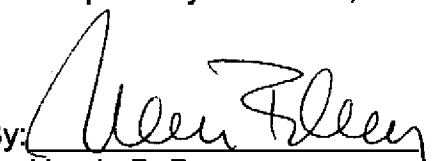
None of the references discloses a method as claimed to provide a vaccine for cats with modified "gag" and "env" genes as claimed.

In view of the above presented remarks and amendments, it is respectfully submitted that all claims on file should be considered patentably differentiated over the art and should be allowed.

Reconsideration and allowance of the present application are respectfully requested.

Should the Examiner consider necessary or desirable any formal changes anywhere in the specification, claims and/or drawing, then it is respectfully requested that such changes be made by Examiner's Amendment, if the Examiner feels this would facilitate passage of the case to issuance. If the Examiner feels that it might be helpful in advancing this case by calling the undersigned, applicant would greatly appreciate such a telephone interview.

Respectfully submitted,

By: 

Ursula B. Day
Attorney For Applicant
Reg. No: 47,296

Date: November 25, 2008
708 Third Avenue
Suite 1501
New York, N.Y. 10017
(212) 904-1815
UBD:be